



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 14, 2016

Maria Pilar Herrero
Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

Subject: Pesticide Registration Improvement Act (PRIA) Labeling Amendment – Acceptable Addition of New Uses for Tomatoes and Peppers
Product Name: LEAP Biological Insecticide Emulsifiable Suspension
EPA Registration Number: 73049-500
Application Date: December 22, 2015
OPP Decision Number: 512561

Dear Ms. Herrero:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable under FIFRA section 3(c)(7)(B).

You must comply with the following conditions:

1. Submit and/or cite all data required for registration or registration review of your product under FIFRA when the U.S. Environmental Protection Agency (EPA) requires all registrants of similar products to submit such data.
2. Be aware that proposed data requirements have been identified in a Final Work Plan. For more information on these proposed data requirements, you may contact the Team Leader for microbial pesticides: <https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-biopesticides-and-pollution-prevention>.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, the EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e).

If you have any questions, please contact Andrew Reighart of my team by phone at (703) 347-0469 or via email at reighart.andrew@epa.gov.

Sincerely,

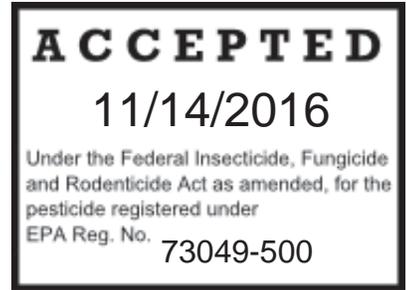
A handwritten signature in blue ink that reads "Andrew C. Bryceland". The signature is written in a cursive style.

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

LEAP™
BIOLOGICAL INSECTICIDE
EMULSIFIABLE SUSPENSION

BACTERIAL DISEASE MANAGEMENT



Active Ingredient:

| | |
|---|--------|
| <i>Bacillus thuringiensis</i> , subsp. <i>kurstaki</i> , strain ABTS-351, fermentation solids, spores, and insecticidal toxins..... | 25.5% |
| Methyl Salicylate..... | 5.9% |
| Other Ingredients..... | 68.6% |
| Total..... | 100.0% |

The percent active ingredient does not indicate product performance and the potency measurements are not Federally standardized.

KEEP OUT OF REACH OF CHILDREN
CAUTION

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

List No.
Lot No.
EPA Reg. No. 73049 - 500
EPA Est. No.

NET CONTENTS: 1 or 2.5 GALLONS

| FIRST AID | |
|---|--|
| If on skin or clothing | <ul style="list-style-type: none"> • Take off contaminate clothing. • Rinse skin immediately with plenty of water for 15 - 20 minutes. • Call a poison control center or doctor for treatment advice |
| If in eyes | <ul style="list-style-type: none"> • Hold eyes open and rinse slowly and gently with water for 15 - 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice. |
| Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals | |
| HOTLINE NUMBER | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-Valent. | |
| NOTE TO PHYSICIAN | |
| Contains petroleum distillate - vomiting may cause aspiration pneumonia. | |

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)
CAUTION**

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

Personal Protective Equipment

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Chemical-resistant gloves, such as barrier laminate, or nitrile rubber, or neoprene rubber or viton.
- Shoes plus socks.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements in the Worker Protections Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco products or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

This product must not be applied aerially within ¼ mile of any habitats of endangered species or threatened Lepidoptera. No manual application can be made within 300 feet of any threatened or endangered Lepidoptera.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Do not enter treated areas without protective clothing until sprays have dried.

MODE OF ACTION

Insecticide: After eating a lethal dose of LEAP, larvae stop feeding within the hour, and will die within several days. Dying larvae move slowly, discolor, then shrivel, blacken and die.

Bacterial Management: LEAP contains methyl salicylate, a known inducer of host plant resistance. Use of methyl salicylate in a preventative manner can trigger a defense response independent of infection, enhancing the plant's ability to fight infection, thus preventing, or suppressing pathogen damage.

LEAP may be used in either the field or greenhouse for the control of any labeled pest.

GENERAL INSTRUCTIONS

LEAP is a highly selective insecticide for use against listed caterpillars (larvae) of Lepidopterous insects. Close scouting and early attention to infestations is highly recommended. Larvae must eat deposits of LEAP to be affected. Use of LEAP will also induce a systemic response in treated plants, enhancing the ability of the plant to resist disease infection and spread. Always follow these directions:

- Treat when larvae are young (early instars) and before economic thresholds of damage have been exceeded.
- Larvae must be actively feeding on treated, exposed plant parts.
- Thorough spray coverage is needed to provide a uniform deposit of LEAP where larvae feed and for maximal disease control. For some crops directed drop nozzles by ground machine are required. As crop matures and the canopy increases in size, increase water volume to ensure complete foliage coverage.
- LEAP does not need an adjuvant to deliver consistent performance of pests/diseases claimed on the label. However, if adjuvant(s) must be utilized because of other crop protection products in the tank mix, the following must be followed: a) Ensure that the adjuvant to be utilized does not adversely change the chemical and physical properties of the tank mixture contents b) Utilize only adjuvants that comply with certification program and standards of the Chemical Producers and Distributors Association (CPDA). c) Apply the mixture to a small portion of the field (<0.5 Acre) to verify that no adverse crop responses are generated from the addition of the adjuvant to the tank mixture d) The variation among types of surfactants, manufacturers and responses to crop safety driven by variety specifics are difficult to evaluate and therefore adverse effects can be potentially generated by adding a surfactant without previous testing on a crop, specific variety and phenological stage.
- Under heavy pest population pressure, use the higher label rates, shorten the spray interval, and/or increase spray volume to improve coverage.
- Repeat applications at an interval sufficient to maintain control, usually 5 to 14 days depending on plant growth rate, moth activity, rainfall after treating, and other factors. If attempting to control a pest with a single application, make the treatment when egg hatch is essentially complete, but before economic crop damage occurs.
- For bacterial pathogen suppression, LEAP must be applied before the disease is observed in the field. For best results, use as part of a plant pathogen control program in rotation or tank

mixed with other commercial crop protectants in a preventative manner. If disease is already present in the field, LEAP should be tank mixed with other registered crop protectants to ensure adequate control.

- LEAP is a non-restricted use pesticide and does not require a restricted use permit for purchase or use.

LEAP may be tank mixed with other labeled insecticides and fungicides as needed or recommended by a certified crop consultant or crop specialist. Use of the resulting tank mix must be in accordance with the more restrictive label limitations and precautions. No dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing. Before tank mixing LEAP with other labeled products, check for tank mix compatibility.

Crop tolerance: Crop tolerance is acceptable for all crops on the label, however phytotoxic response has not been evaluated for all possible rotational and tank mix combinations under all conditions. When possible, test on a small section of crops to ensure no phytotoxicity will occur under your conditions.

GROUND APPLICATIONS

LEAP may be applied in ground equipment with quantities of water sufficient to provide thorough coverage of infested plant parts. The amount of water needed per acre will depend on crop development, weather, application equipment, and local experiences.

Do not spray when wind speed favors drift beyond the area intended for use.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all of these factors when making application decisions.

Mixing Recommendations: Important - do not add LEAP to the tank before introducing at least a third of final volume of water to be applied. Start the mechanical or hydraulic agitation to provide moderate circulation before adding LEAP. Add the desired volume of LEAP to the mix tank and continue circulation. Include rinse water from the container. Maintain the suspension while loading and spraying. Do not mix more LEAP than can be used in a 1-day period. Do not leave mixed material in the tank overnight. Rinse and flush spray equipment thoroughly following each use. Selection of fluid to flush the application system will depend on what type of mixture was used during the application period. Use a strainer no finer than 50 mesh in conventional spray systems.

The physical compatibility of LEAP with other agricultural products should be evaluated before tank mixing for field use. Using a quart or larger jar, add the field proportional amounts of water volume and each product and mix well. If the materials remain mixed and in a true suspension

after 5-10 minutes without forming any type of abnormal mixture composition, or can be re-mixed readily, then the materials are compatible for tank mixture.

CAUTION:

LEAP should not be used in combination with Comite[®], Captafol, or Dyrene[®].

Spray Volume Recommendations: For conventional ground application, use sufficient spray volume to ensure complete coverage of the plants, at least 20 gallons of volume per acre.

Pests controlled by LEAP

| Common name | Scientific name |
|---------------------------------------|--|
| Achema Sphinx Moth (Hornworm) | <i>Eumorpha achemon</i> |
| Armyworm | <i>Spodoptera spp., e.g. exigua, frugiperda, littoralis, Pseudaletia unipuncta</i> |
| Cherry Fruitworm | <i>Grapholita packardi</i> |
| Cotton Bollworm | <i>Helicoverpa zea</i> |
| Cranberry Fruitworm | <i>Acrobasis vaccinii</i> |
| Cross-striped Cabbageworm | <i>Evergestis rimosalis</i> |
| Cutworm | <i>Various Noctuid species, e.g. Agrotis ipsilon</i> |
| Diamondback Moth | <i>Plutella xylostella</i> |
| Ello Moth (Hornworm) | <i>Erinnyis ello</i> |
| Grape Berry Moth | <i>Paralobesia viteana</i> |
| Grape Leafroller | <i>Platynota stultana</i> |
| Grapeleaf Skeletonizer (ground only) | <i>Harrisina americana</i> |
| Green Cloverworm | <i>Plathypena scabra</i> |
| Gypsy Moth | <i>Lymantria dispar</i> |
| Hornworm | <i>Manduca spp.</i> |
| Imported Cabbageworm | <i>Pieris rapae</i> |
| Looper | <i>Various Noctuidae, e.g. Trichoplusia ni</i> |
| Melonworm | <i>Diaphania hyalinata</i> |
| Obliquebanded Leafroller | <i>Choristoneura rosaceana</i> |
| Omnivorous Leafroller | <i>Platynota stultana</i> |
| Orange Tortrix | <i>Argyrotaenia citrana</i> |
| Rindworm complex | <i>Various Lepidoptera.</i> |
| Saltmarsh Caterpillar | <i>Estigmene acrea</i> |
| Soybean Looper | <i>Pseudoplusia includens</i> |
| Spanworm | <i>Ennomos subsignaria</i> |
| Tent Caterpillar | <i>Various Lasiocampidae</i> |
| Tobacco Budworm | <i>Heliothis virescens</i> |
| Tobacco Hornworm | <i>Manduca sexta</i> |
| Tobacco Moth | <i>Ephestia elutella</i> |
| Variegated Cutworm | <i>Peridroma saucia</i> |
| Velvetbean Caterpillar | <i>Anticarsia gemmatalis</i> |
| Southern cornstalk borer | <i>Diatraea crambidoides</i> |
| Sugarcane borer | <i>Diatraea saccharalis</i> |
| Corn earworm, cotton bollworm, tomato | <i>Helicoverpa zea</i> |

| Common name | Scientific name |
|-----------------|----------------------------|
| fruitworm | |
| Tobacco budworm | <i>Heliothis virescens</i> |

APPLICATION RATE

| Field Crops | Application rate (Quarts/Acre) |
|---|---|
| <p>Tomato and Pepper</p> <p>Refer to <u>adjuvant language</u> in general instructions before deciding to add an adjuvant with Leap</p> | <p>0.5 – 2.0</p> <p>LEAP may be used to control caterpillar pests such as small armyworms and fruitworms when populations are light and full coverage sprays are applied.</p> <p>For <i>Xanthomonas</i> spp. and <i>Pseudomonas</i> spp. pathogen suppression, apply preventatively on a 5-10 day schedule. For best disease control, LEAP should be used in tank mix or rotation with other registered pathogen control products, especially if disease is already observed in the crop.</p> |

For Small Spray Volumes:

If Rate Is:

Use This Amount Per Gallon

0.5 quarts/acre in 100 gals
1 quart/acre in 100 gals.
2 quarts/acre in 100 gals.

1 tsp.
2 tsps.
4 tsps.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Keep containers tightly closed when not in use. Do not store at temperatures greater than 100° F. Roll or shake the container before dispensing.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Do not contaminate water when disposing of equipment washwaters.

Container Disposal: Nonrefillable container. Do not reuse this container.

Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact Ag Container Recycling Council at 202-861-3144 or www.acrecycle.org. If recycling is not available puncture and dispose of the container in a sanitary landfill, or by other procedures approved by state and local authorities.

NOTICE TO USER

Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

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